

FEB 14 2002

510(k) Summary**Florence Medical Ltd.****SmartFlow®****510(k) Number K 020127****Submitter's Name:**

Florence Medical Ltd.
Sharona Center
12 Derech Hasharon
Kfar-Saba, Israel
Tel.: 972-9-7431975
Fax: 972-9-7452323
SmartFlow@florence.co.il

Contact Person:

Orly Maor
Push-Med Ltd.
117, Ahuza St., Ra'ananna 43373, Israel
Tel: 972-9-7718130
Fax: 972-9-7718131

Trade Name:

SmartFlow®

Classification Name:

Computer, Diagnostic, Programmable

Classification:

Computer, Diagnostic, Programmable are class II devices (Product Code DQK).

Predicate Device:

The SmartFlow® with the Pulse Transmission Coefficient software is substantially equivalent to the SmartFlow® (Florence Medical Ltd.) cleared under K003122 and K012947.

Indication for use:

Florence Medical Ltd. SmartFlow® is intended for use in coronary and peripheral vasculature in conjunction with pressure measurement devices during and after diagnostic procedures, such as angiography, or interventional procedures, such as angioplasty, to evaluate the hemodynamic status of the diseased arteries and to provide further clinical information in the diagnosis and treatment of both coronary and peripheral artery diseases.

Device Description:

The SmartFlow® with the Pulse Transmission Coefficient software is a tool for measuring coronary and peripheral vasculature hemodynamic status patterns during diagnostic and interventional procedures.

The SmartFlow® is a PC based system comprising of a full color display with a touchscreen for patient data entry and control, and software calculations of the CFR and FFR parameters. The display and touchscreen are mounted in a shielded metal housing.

Substantial Equivalence:

The SmartFlow® with the Pulse Transmission Coefficient software is substantially equivalent to the former cleared models of the SmartFlow®. In fact, it is an improved model of the SmartFlow® that includes application to calculate the transmission of high-frequency components of the pressure signal through a stenosis above the FFR/CFR and Multiple Lesion case analysis.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Florence Medical Ltd
c/o Mr. Orly Maor
Vice President
Push-med Ltd.
117 Ahuzah St.
Ra'ananna 43373
ISRAEL

Re: K020127

Trade Name: Florence Medical Ltd. SmartFlow® device with Pulse Transmission
Coefficient software

Regulation Number: 21 CFR 870.1425

Regulation Name: Programmable Diagnostic Computer

Regulatory Class: Class II (two)

Product Code: DQK

Dated: January 10, 2002

Received: January 15, 2002

Dear Mr. Maor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

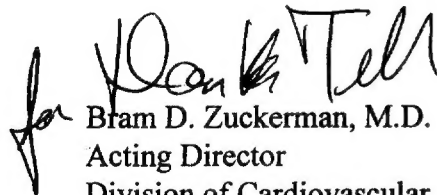
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K020127


Device Name: SmartFlow®

Indications for Use:

The SmartFlow® is intended for use in coronary and peripheral vasculature in conjunction with pressure measurement devices during and after diagnostic procedures, such as angiography, or interventional procedures, such as angioplasty, to evaluate the hemodynamic status of the diseased arteries and to provide further clinical information in the diagnosis and treatment of both coronary and peripheral artery diseases.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K020127

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over the Counter Use ☐